



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2012-M-1012, FDA-2012-M-1039, FDA-2012-M-1048, FDA-2012-M-1049, FDA-2012-M-1066, FDA-2012-M-1084, FDA-2012-M-1085, FDA-2012-M-1088, FDA-2012-M-1109, FDA-2012-M-1110, FDA-2012-M-1111, FDA-2012-M-1146, FDA-2012-M-1176, FDA-2012-M-1183, and FDA-2012-M-1184]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the

SUPPLEMENTARY INFORMATION section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2012, through December 31, 2012. There were no denial

actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

Table 1.--List of Safety and Effectiveness Summaries for Approved PMAs Made Available From October 1, 2012, Through December 31, 2012

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P110038, FDA-2012-M-1012	Bolton Medical Inc.	Relay® Thoracic Stent-Graft with Plus Delivery System	September 21, 2012
P110042, FDA-2012-M-1048	Cameron Health, Inc.	Subcutaneous Implantable Defibrillator (S-ICD®) System	September 28, 2012
P100003, FDA-2012-M-1039	Globus Medical, Inc.	Secure-C Artificial Cervical Disc	September 28, 2012
P120005, FDA-2012-M-1049	Dexcom, Inc.	Dexcom G4 PLATINUM Continuous Glucose Monitoring System	October 5, 2012
P120006, FDA-2012-M-1110	TriVascular, Inc.	Ovation Abdominal Stent Graft System	October 5, 2012
P120007, FDA-2012-M-1066	Gen-Probe, Inc.	APTIMA® HPV 16 18/45 Genotype Assay	October 12, 2012
P110008, FDA-2012-M-1085	Paradigm Spine, LLC	coflex® Interlaminar Technology	October 17, 2012
P110039, FDA-2012-M-1084	InSightec, Inc.	InSightec ExAblate® System	October 18, 2012
P110021, FDA-2012-M-1088	Edwards Lifesciences, LLC	Edwards SAPIENT™ Transcatheter Heart Valve	October 19, 2012
P100040/S008, FDA-2012-M-1109	Medtronic Vascular	Valiant® Thoracic Stent Graft with the Captivia Delivery System	October 26, 2012
P100012, FDA-2012-M-1111	NuVasive, Inc.	PCM® Cervical Disc System	October 26, 2012
P120002, FDA-2012-M-1183	Cordis Corporation	S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems	November 7, 2012
P100022, FDA-2012-M-1146	Cook, Inc.	Zilver PTX Drug-Eluting Peripheral Stent	November 14, 2012
P100047, FDA-2012-M-1184	HeartWare, Inc.	HeartWare® Ventricular Assist System	November 20, 2012
P120008, FDA-2012-M-1176	Abbott Laboratories	ARCHITECT AFP Assay, ARCHITECT AFP Calibrators and ARCHITECT AFP Controls	November 28, 2012

II. Electronic Access

Persons with access to the Internet may obtain the documents at

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm>.

Dated: March 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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